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Sucrose

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered :

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC*</u>
J.T.Baker®	6320	Sucrose NF, Multi-Compendial	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

A number of the cGMP produced products that are sold by Avantor Performance Materials, LLC. may not be originally manufactured at our sites. However, we perform the analytical and stability testing for these products and repackage the products where applicable. With ISO and cGMP procedures in place at our facilities we can ensure, and take complete responsibility for, the traceability and quality of the finished, packaged product that we offer.

The original manufacturer and address will be referenced on the Certificate of Analysis as an alpha or alpha-numeric manufacturer code rather than listing the full name and address. This practice is compliant with both ICH Q7 Good Manufacturing Guidance for Active Pharmaceutical Ingredients (APIs) and IPEC guidelines and it meets cGMP requirements. For instructions to decipher the manufacturer reference code please consult our website. Instructions can be found in the Ask Avantor QA Center of the support section of our web site or by directly linking to Ask Avantor Keyword: Manufacturer Code.

Section 3 – Physical/Chemical Information

CAS #: 57-50-1

Manufacturing Process:

Purification

Raw Material Origin:

Plant

Section 4 – Regulatory Information

Compendial Compliance: Please see the current product specifications at www.AvantorInc.com.

DMF:

Avantor Performance Materials, Inc. does not carry a Drug Master File for these products.

BSE/TSE Status:

Sucrose is not derived from animal-based raw materials. However, the raw material sucrose DOES come into contact with animal bone charcoal (bone char) during the refining process.

The manufacturing process of the bone char is such that virtually all organic matter is destroyed, leaving only the inert granular substance called natural charcoal. During manufacturing of the bone char, the bone char supplier confirms that clean, sun dried, Specific Risk Material (SRM) free, crushed cattle bone is heated to 1000°C over an 8 hour period, in a reducing atmosphere. The production of bone char uses only raw materials (bovine) sourced from one, or a combination, of the following regions: Brazil and Mexico. The bone char supplier has confirmed that all raw materials are SRM free- all skulls, spinal cords and spinal columns have been removed.

We further purified the resultant sucrose material chromatographically.

Based on our knowledge of the raw materials and processes used in the manufacture of cane sugar products and our sucrose purification process, BSE is not an issue for the finished product.

Allergen/Hypersensitivities Information:

The products listed do not contain cereals containing gluten (i.e. wheat, rye, oats, barley, spelt, kamut or their hybridized strains), malt, triticale, gluten, other grains, corn, soy, soybeans, eggs, yeast, canola, milk, dairy products, fish, crustacean shellfish, seafood products, tree nuts, peanuts, nut products (i.e. Almond (*Amygdalus communis* L.), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinensis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*)), seed products (sesame seeds and products thereof), natural grape products, natural flavors, artificial flavors, celery, mustard, lactose, sulfites, elemental sulfur, preservatives, lupine and products thereof, MSG, disodium guanylate/inosinate, artificial sweeteners, phenylalanine, additives, colorants, dyes, or natural rubber (latex). These products are manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other products.

GMO Information:

To the best of our knowledge, the subject materials, including any raw materials and processing aids, are NOT subject to genetic modification.

Residual Solvents/Organic Volatile Impurities (OVI) Information:

Only the Class 2 solvent Methanol and the Class 3 solvent Ethanol and Isopropanol are likely to be present. Each is tested and the concentration reported for each batch.

Elemental Impurities:

Aflatoxins:

Aflatoxins as defined by IPEC (International Pharmaceutical Excipient Council) are a group of structurally related toxic compounds produced by certain strains of the fungi *Aspergillus flavus* and *A. parasiticus*. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. Aflatoxicosis is poisoning that results from ingestion of aflatoxins in contaminated food or feed.

Avantor does not analyze the product(s) for the presence of aflatoxin content, does not maintain a specification for aflatoxin and cannot provide any guarantee of complete absence in the product due the nature of aflatoxins.

Kosher Status:

The subject materials are not Kosher Certified.

Please refer to the customer support section of our website for our most up to date listing of Kosher products. (Ask Avantor Keyword: Kosher)

Halal Status:

The subject materials are not Halal Certified.

Please refer to the customer support section of our website for our most up to date listing of Halal products. (Ask Avantor Keyword: Halal)

GRAS Status:

These products have not been assessed for GRAS Status.

Section 5 – Miscellaneous Product Information

Certificate of Analysis Date Format: The Manufactured Date and Expiration/Retest Date on the C of A are reported as YYYY/MM/DD from our ERP system effective April 30, 2012. For example, the Manufactured Date for October 1, 2012 would be reported as 2012/10/01

Lot Numbering System and Batch Description: Please refer to the customer support section of our website for information concerning our lot/batch numbering system. (Ask Avantor Keyword: Lot Number)

Batch Definition: A “batch” is a homogeneous unit of production; each batch of material is from one single batch of the source supplier.

Shelf Life Information: If a product has an assigned expiration or retest period, the date will appear on the certificate of analysis. For products that do not have assigned dates please contact Technical Support through the customer support section of our website for our product stability profiles. (Ask Avantor Keyword: Expiration)

Management of Change: Please refer to the customer support section of our website for information concerning our Management of Change program. (Ask Avantor Keyword: MOC)

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. Please contact our Trade Compliance Department if you require further documentation. (Trade.Compliance@AvantorInc.com)

Storage Requirements: Please refer to the product Certificate of Analysis/Product Specifications. In the absence of specific storage conditions listed on the Avantor specification sheet or certificate of analysis, our products are to be stored in ambient conditions of temperature and humidity. We do not formally tie any specific temperature or humidity range with the ‘ambient’ storage designation, but an example of a common temperature interpretation is 15-30°C. Our products are also packaged to protect from the normal variation in humidity during storage and shipment. Further handling and storage information may be found in Section 7 of the product SDS sheet.

Section 6 – Revision History

Rev. 0; March 11, 2014 – IPEC EIP format. (MCH)

Rev. 1; August 13, 2014 – Section 4: Updated BSE/TSE information to reflect information provided per MOC-PROC-2140; Updated Residual Solvents to include Isopropyl Alcohol. (MCH)

Rev. 2; Feb. 9, 2016 – Section 1: update product name. (MCH)

Rev. 3; May 19, 2017- Updated template to reflect new Avantor logo and company information. Section 4: Removed Residual Metallic Catalysts Statement; added Aflatoxin statement; added Elemental Impurities statement. Section 5: Added Country of Origin Statement; added Storage Requirement Statement. Section 7: Updated Contact information. (CMG)

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service

Phone: 1-855-282-6867

1-610-573-2600 (outside U.S.)

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CS.Specialist@AvantorInc.com



Technical Service

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The most current revision of this document is maintained on our website. Reviews and revisions are performed as warranted due to product changes or as part of the supplier audit cycle.

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Material Name: Sucrose (cane derived) **Product codes:** : 6320 **Date:** September 29, 2016

Source/Type of Excipient: ☐ Mineral; ☐ Mineral derived; ☐ Plant; ☒ Plant derived; ☐ Synthetic; ☐ Fermentation derived

Other (explain):

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014



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